REMARKS

The amendments to the claims do not add new matter. Claim 26 has been amended to recite "said assembled bone graft assembled outside the body and suitable for implantation into a human patient." The latter portion of the above phrase "suitable for implantation into a human patient" has been moved from the end of claim 26 to the beginning. Hence, it does not add new matter. The first portion of the phrase "said assembled bone graft assembled outside the body" is actually inherent as a result of the latter phrase that the "assembled graft" pre-exist outside the body to be "suitable for implantation into the body." Further support for the "assembled graft" existing in assembled form outside the body is found throughout the specification, including the description of each of Figures 2-22, at page 3, line 27 to page 4, line 6, referring to the depicted "assembled implant" according to this invention.

Separately, each of claims 26-34 has been amended to reflect that the allograft bone portions are "machined" to have a predetermined shape. Support for the bone portions of the assembled allograft being "machined" is found throughout the specification, including at page 5, lines 25-27 ("The assembled pieces may first be machined to desired dimensions and shapes, prior to assembly, the assembled implant may be machined, or both.").

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Objection /Rejection

Claims 26-34 and 60-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

Each of these five (5) bases for rejection is addressed in Sections I-V, respectively, which follow.

I. Obviousness Type Double Patenting

Claims 26-34 and 61-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The Applicants will address this issue at such time as claims are allowed in the present application. Applicants are considering cancelling claim 79 in the copending application.

II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)

A. Ellis does not teach a "machined" portion of bone

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Each of claims 26-34 has been amended to recite as an element that the bone portions of the assembled bone graft are "machined" to have a predetermined shape. Ellis simply discloses reattaching a single fractured piece of bone to the "adjacent underlying bone mass" from which it originally fractured. [See Ellis at col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condoyle 201 and an **adjacent underlying bone mass** 202."); emphasis added in bold.] Because the bone fragment of Ellis fractured, it is already the perfect shape to fit the location from whence it came. At no time does Ellis disclose machining the fractured bone piece into another shape. For this reason, claims 26-34 would not be anticipated by Ellis.

B. Ellis does not disclose an assembled bone graft that exists in assembled form outside the body

Each of claims 26-34 includes as a limitation that the "**assembled bone graft**" be "**assembled outside the body and suitable for implantation into a human patient**" (claim 26) or that the "assembled bone graft" be "**suitable for implantation into a human patient**" (claims 27-34). In Ellis, only a single bone portion is shown as a fractured fragment. It may be argued that the single fractured fragment exists as a part of an assembled bone (but not "graft") inside the body. However, that single bone fragment portion never exists in "assembled" form outside the body as an "assembled bone graft" that is "suitable (in assembled form) for implantation into a human patient." For this reason also, claims 26-34 would not be anticipated by Ellis.

In addition, each of claims 26-34 recites as an element that the "assembled bone implant" that is "suitable for implantation in a human patient" include **two or more** "bone portions." In contrast, Ellis only discloses a **single** bone fragment that is re-affixed to the underlying position from where it fractured. The single fractured piece of bone of Ellis is never assembled to another portion of bone outside the body so as to be suitable for implantation into a human patient. Moreover, as discussed in Section (I)(A) *supra*, the fragment of Ellis is not "machined" to have some predetermined shape. Hence, Ellis never discloses the existence outside the body of an "implantable bone graft" comprising a **machined first bone portion** and a **machined second bone portion**. For theses reasons also, claims 26-34 would not be anticipated by Ellis.

C. Ellis does not teach or suggest a "graft" as the term is understood in the art

Claims 26-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Claims 26-34 are directed to an "assembled bone graft. . . ." According to the Patent Office, "Ellis anticipates the claim language where the bone pieces or bone portions of the **same** patient are grafted back **onto the bones they were separated from** to form a graft. . . ." [Official Action at pages 3-4, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] The word

"graft" **never** appears in Ellis and it is for a good reason. As a person skilled in the art, Ellis knew that he was not "grafting" when he re-attached a fragment of bone to the **same** site from which it fractured. In the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to the location that it was "**separated from,**" i.e., the **same** location. Also in FIGs 2a-2d and FIGs. 3 and 4 of Ellis, Ellis discloses binding a single "bone fragment" to the **same** (underlying) "bone mass" from which it separated. [See Ellis at col. 4, lines 16-18 ("FIG. 2a depicts a femur 20 which contains a fractured condoyle 201 and an **adjacent underlying bone mass** 202."); emphasis added in bold.] As support for the Patent Office's position that the separated "bone fragment" of Ellis is a "graft," the Patent Office cites to Stedman's Medical Dictionary, 23rd Edition (1976) at page 599 for the definition of "graft" as "anything **inserted** into something else so as to become an integral part of the latter." [Official Action at page 4; emphasis added in bold.]

However, if Ellis is actually disclosing a "bone graft," as alleged by the Patent Office, and the source of bone is clearly from the same patient (autogenous), then the more relevant definition in the PTO's own authoritative reference (i.e., Stedman's Medical Dictionary, the same page is "autogenous bone graft." Under this definition, such a "bone graft" comes from "**one part of the body to another**":

> autogeneous bone graft- a bone g[raft] from one part of the body to another.
>
> [Stedman's Medical Dictionary, 23rd Edition, (1976) at p. 599; emphasis added in bold.

Because the bone in Ellis is from the same patient, it is clearly "autogenous." However, the bone repair described in Ellis, does not satisfy the remaining portion of the definition of "bone graft" because the bone is not "from one part of the body to another." One skilled in the art recognizes that the graft from one part of the body is a "shaped" piece that is shaped to fit another. Because the bone in Ellis has its natural shape and is fixed to its original location, it is a repair and not a "bone graft" even as that term is defined in the Patent Office's own reference. For this reason also, Ellis is not anticipatory of claims 26-34.

III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)

Claims 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, "Ellis discloses using 'any number of pins or screws' to secure the bone portions together but not the use of 'four' pins as claimed." [Official Action at page 5.] The Patent Office then contends that "the use of 'four' pins would have been considered prima facie obvious to an ordinary artisan. [Official Action at page 4.] The Applicants respectfully submit that the cited reference fails to make a *prima facie* case of obviousness against the present invention.

As an initial matter, claims 61 and 62 are ultimately dependent upon claims 31 and 33, respectively. As dependent claims, claims 61 and 62 incorporate all of the limitations of the base claim and any intervening claims. Independent claims 31 and 32 include as an element "machined" bone portions of "allograft" bone "suitable for implantation into humans." [See Section II(A) *supra*.] The single bone fragment of Ellis in not "machined." It is used in its natural shape so as to fit the point of fracture like a piece of a puzzle. For this reason, claims 61-62 would not have been obvious over Ellis.

Separately, in Ellis, the fragment of bone that is re-attached to the site from which it fractured is "living" bone. One skilled in the art recognizes that the "**living**" (autograft) bone of Ellis is structurally different than the "allograft" bone of the Applicants' invention, which is processed to be "**non-living**" by removal of all foreign antigens and living cells, which could evoke an immune response, to render the "assembled bone graft" "suitable for implantation into a human patient." [See Exhibit D: Spine School at page 2, para.2.] Thus, even if Ellis could be construed as suggesting the use of 4 pins, Ellis would not have rendered obvious the Applicants' invention as a whole because Ellis never taught or suggested the use of dead and processed bone tissue.

Finally, Ellis never teaches or suggests a graft that is "assembled" outside the body so as to be an "assembled bone graft suitable for implantation into a human patient." [See Section II(B) *supra*.] Rather in Ellis, the only "assembled bone" exists exclusively as part of the body because the main bone mass to which a fragment is re-

attached is part of the living human body. For any one of these reasons, claims 61-62 would not have been obvious over the disclosure in Ellis.

IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis

Claims 26-27, 31-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, "Ochoa discloses bone portions or pieces **grafted back onto the bones they were separated from** . . ." [Official Action at page 5, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (*i.e.*, the location that it was "**separated from**"). In the same sentence, the Patent Office admits that Ochoa "**fails to clearly disclose the use of a plurality of pins as now claimed.**" [Official Action at page 5; emphasis added in bold.] To make up for this admitted deficiency, the Patent Office cites to Ellis for allegedly teaching that "it was well known to use a plurality of pins to attach bone pieces together." [Official Action at page 5; emphasis added in bold.] The Applicants respectfully submit that the cited combination fails to make a *prima facie* case of obviousness against the presently claimed invention.

In particular, each of independent claims 26-27, 31-34 and 61-62 has been amended to recite that the two or more bone portions therein are "machined" portions of allograft bone. In Ellis and Ochoa, the bone fragment and fragments, respectively, retain their natural shape at the interface of the fracture(s), respectively. They are not machined to a predetermined shape. Because, the combination of Ochoa and Ellis fails to teach any "machined" bone portions, claims 26-27, 31-34 and 61-62 would not have been obvious over Ochoa in view of Ellis. Separately, it should be pointed out for the record that the bones in Ochoa are living, although for purposes of clarity, they shown separate from the muscle, tendons, veins and arteries. It is the fixation device of Ochoa which is implantable. See Claim 1 of Ochoa.

Claims 26-27, 31-34 and 61-62 also include the limitation that the assembled bone graft, which is comprised of two or more portions of allograft bone, be "suitable for implantation in a human patient." To be suitable for implantation in a human patient, the "allograft" bone (which is "genetically distinct" as admitted by the Patent Office[1]) is processed to remove all living cells, such that it is **non-living**. [Exhibit D: Spine School at page 2, Para 2.] In addition, it has been processed to remove fat and proteins, the latter of which would be recognized as foreign and rejected by the graft recipient. Unless "allograft" bone is non-living and has been processed to remove foreign antigens (i.e., proteins and cells) it would not be suitable for use in humans. In marked contrast, both Ochoa and Ellis, as acknowledged by the Patent Office, teach how to re-attach a fractured fragment of **living** bone back to its original **living** bone mass. Neither Ochoa nor Ellis teaches or suggest the use of "allograft" bone that has been processed (to death) to be "suitable for implantation in a human patient." For any and all of these reasons, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

Separately, each of the Applicants' claims is directed to an "**assembled** bone graft" that is "suitable for implantation into a human patient." By use of the adjective "assembled," the "assembled bone graft" that is "suitable for implantation in a human patient," must exist in "assembled" form **outside** the body of a human patient to be "suitable for implanting into a human patient." In contrast, in both Ochoa and Ellis, the "assembled" bone species only exists in "assembled" form **inside** and as part of the living body of the human patient because it is assembled *in vivo*. Hence, at no time does Ochoa or Ellis teach or suggest an "assembled bone graft" (that exists in assembled form outside the body) so as to be "suitable for implantation into a human patient." For this reason also, the combination of Ochoa and Ellis would fail to make a *prima facie* case of obviousness against claims 26-27 and 31-34 or their dependents (claims 61 and 62).

[1] "'Allograft' is a homograft (i.e., from the same species) that is allogeneic (i.e., genetically distinct) to the recipient." [Official Action at page 4, lines 4-5.].

V. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates)

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Siebels discloses "an assembled bone implant made by assembling separate bone implant pieces together by aligning bores of adjacent pieces;" and introducing "pins into the aligned bones to hold the implant pieces together." [Official Action at page 6.] The Patent Office admits that "Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic . . . or carbon-fiber reinforced plastic. . . ." [Official Action at page 6.] To make up for this deficiency, the Patent Office cites to Coates, alleging that Coates "teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61." [Official Action at page 6.] The Patent Office then concludes that it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same. The Applicants respectfully disagree.

As acknowledged by the Patent Office, Siebels acknowledges that Siebels "mentions a preference for fiber-reinforced plastic . . . or carbon-fiber reinforced plastic. . . ." [Official Action at page 6.] The mentioned preference for plastic is over metal because "the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of image-producing methods (CT*, MR*) [Translator's note: CT = charge transfer (absorption band of electron-transfer band); MR + magnetic resonance)." [Translation at page 6.] One skilled in the art recognizes that the referenced "scattering of rays" refers to both X-rays and magnetic field lines which would be influenced by the presence of a metal implant. Notwithstanding the PTO's translation of CT as "charge transfer," one skilled in the art recognizes that this translation is erroneous and that CT refers to the x-ray technique of "computed tomography" which would be

obstructed by a metal implant. Thus, Siebels teaches a preference for reinforced plastic over metal implants.

Coates teaches a preference for cortical bone implants over metal implants. In particular, Coates states "bone as an implant also allows excellent post-operative imaging because it **does not cause scattering like metallic implants** on CT or MRE imaging." [Coates at col. 2, lines 63-65; emphasis added in bold.] However, neither Siebels nor Coates, alone or in combination, teaches or suggests a preference for the bone of Coates over the reinforced plastic of Siebels. Even assuming for the sake of argument that it would have been "obvious to try", "obvious to try" is not the test for obviousness. *See In re Goodwin,* 198 USPQ 1 (CCPA 1978) ("However, this court has consistently refused to recognize obvious to try rejections. As we have said many times, obvious to try is not the standard of 35 USC 103. . .").

A. The Combination of Siebels and Coates Fails to Provide a "Suggestion to Combine" or a Reasonable Expectation of Success

In order for an invention to be obvious, "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." *Amgen v. Chugai,* 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can "**easily be manufactured** for a **multiplicity of overall dimensions**:"

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a **multiplicity of overall dimensions**, forms the basis of the [proposed] invention.
>
> In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.
>
> [English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the "ease" of manufacturing, Siebels relies upon cutting discs out of "prefabricated solid or hollow strand." [English Translation of Siebels at page 3, line 7.]

Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of "fiber reinforced plastic" provides for "manufacturing" in an "**extraordinarily easy way**":

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be **manufactured** in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an **extraordinarily easy way**." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "**easy**" but "**extraordinarily easy**."

In addition, the above quote from Siebels teaches that "**fiber orientation**" is important because it "imparts an **optimal rigidity**." The word "**optimal**" is a superlative and means "most favorable or desirable; best; optimum." [Exhibit G: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, **fiber orientation** is a necessary element in the material used by Siebels to "impart **optimal** rigidity."

In contrast to the "extraordinarily easy" method of manufacturing disclosed in Siebels (that provides for an implant having "optimal rigidity"), Coates discloses that "developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible**." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant

material" for spinal implants. Rather, it was considered "**extremely difficult or impossible**" to provide an implant that had the benefits of both bone and metal without their undesired properties. The words "extremely difficult or impossible" are **superlatives** related to difficulty or impossibility. Given this "**extremely difficult or impossible**" setting of developing an implant from cortical bone, one skilled in the art would not have been motivated to substitute the "**extremely difficult or impossible**" cortical bone of Coates for the "**extraordinarily easy**" fiber reinforced plastic of Siebels. Moreover, given the teaching in Coates of the "**extreme difficulty or impossibility**" of developing a **single piece** implant from cortical bone, one skilled in the art would have been even **less motivated** to build an implant assembled from little pieces of cortical bone held together with pins, than from the "**extraordinarily easy**" fiber reinforced plastic of Siebels. Moreover, given Coates teaching of the "**extreme difficulty**" in making even a single piece implant from cortical bone, there would **not** have been the requisite reasonable expectation of success that the Applicants' would have been able to make implants assembled from little pieces of cortical bone. See *Amgen v. Chugai*, 18 USPQ2d at 1022. For these reasons, claims 26-34 and 61-62 would not have been obvious under 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

B. The Cited Art Teaches Away from Combining Siebel with Coates

"A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**" *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. In the present case, one skilled in the art, upon reading Siebels "extraordinarily easy" method for producing an implant having "optimal rigidity" due to the fiber orientation would have been led in a direction **divergent** from the "**extremely difficult or impossible**" path of making a single piece implant from cortical bone as disclosed in Coates. Because Siebels led in a divergent direction from the path taken in Coates, Siebels taught away from Coates as a matter of law. *Monarch Knitting*, 45 USPQ2d at 1984. It is "error to find obviousness where references 'diverge

from and teach away from the invention at hand.'" *In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). For this reason also, the combination of Siebels and Coates would have failed to make a prima facie case of obviousness at the time the Applicants' invention was filed.

C. The Prior Art As A Whole Fails to Teach a Plurality of Advantages for the Cortical Bone Implant of Coates

The Patent Office contends that "Coates teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo." [Official Action at page 6.] The Applicants respectfully disagree. Coates teaches that there were numerous difficulties associated with autograft and allograft implants made from cortical bone, including trauma to other sites, sizing, slippage, displacement and permanent neural injury to the patient:

> **Unfortunately, the use of bone grafts presents several disadvantages. Autograft** is available in only limited quantities. The additional surgery also increases the risk of infection and blood loss and may reduce structural integrity at the donor site. Furthermore, some patients complain that the graft harvesting surgery causes more short-term and long-term pain than the fusion surgery.
>
> **Both allograft and autograft present additional difficulties.** Graft alone **may not provide the stability required to withstand spinal loads.** Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to **repeatedly trim the graft material to obtain the correct size** to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. **Migration and expulsion of the graft** may cause **neural and vascular injury**, as well as collapse of the disc space. Even where such slippage does not occur, **micromotion** at the

> graft/fusion-site interface **may disrupt the healing process** that is required for fusion.
>
> [Coates at col. 3, lines 10-32; emphasis added in bold.]

Thus, Coates does teach that there are difficulties associated with implants made from cortical bone which are not described for implants made from fiber reinforced polymer of Siebels.

One of the properties to be considered is the ease of manufacturing the implant. The ease of manufacturing was discussed both in Siebels and in Coates. Siebels teaches that implants made from fiber-reinforced polymer can "**easily be manufactured** for a **multiplicity of overall dimensions [sizes]**":

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a **multiplicity of overall dimensions**, forms the basis of the [proposed] invention.
>
> In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.
>
> [English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

Siebels discloses that his implants can be made in an "**extraordinarily easy way**" and provide "optimum rigidity" and "strength" to the implant:

> Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

In contrast to the "**extraordinarily easy way**" of Siebels, Coates teaches that "developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible**."

[Coates at col. 3, lines 35-39.] Thus, the material and method used to produce the device of Siebels has at least one major advantage ("**easily be manufactured** for a **multiplicity of overall dimensions**") not found in the implant of Coates.

The fiber-reinforced plastic and the carbon-reinforced plastic of Siebels is the same fiber reinforced plastic and the carbon reinforced plastic disclosed in U.S. Pat. 5,192,327 (Brantigan) which is attached as Exhibit H and cited in a cofiled IDS. When Coates addressed its advantages over the prior art, the advantages were in relation to "metal" implants, not the fiber-reinforced implants of Siebels or Brantigan:

> developing an implant having the biomechanical properties of **metal** and the biological properties of bone without the **disadvantages of either** has been **extremely difficult or impossible**.
>
> [Coates at col. 3, lines 35-39.]

Coates fails to address or overcome the stated manufacturing advantages associated with the fiber reinforced plastic of Siebels, so as to motivate one skilled in the art to disregard the ease of manufacturing advantages associated with Siebels. In fact, Siebels states that his preferred embodiment imparts "**optimal rigidity**." [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.] Brantigan also teaches that the fiber- and carbon-reinforced plastic polymers, such as "Peek," are "radiolucent," unlike metal. [Brantigan at col. 3, lines 9-18.] Coates never addressed or showed superiority over the "optimal rigidity" in the implants of Siebel. Coates also never addressed or established a manufacturing advantage over the "**extraordinarily easy way**" in which the implants of Siebels are manufactured. Rather Coates taught the opposite, stating that even Coates large single piece cortical bone implants were "**extremely difficult or impossible**" to manufacture.

Both Coates and Siebels teach that their implants have the same advantage of being radiolucent versus the radio opaqueness of the prior art metal implants. Siebels also teaches that its **preferred embodiment**, which is a fiber (e.g., graphite) reinforced plastic (FRP), has advantages over metals, which are associated with the disadvantageous stress-shielding and radio [X-ray]-opaqueness:

> Preferably the disks are made of a carbon-fiber reinforced plastic (CFP) . . . . The manufacturing of the entire implant of **CFP has the advantage** [over metal] that **the implant does not bring about the scattering of rays**, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of **all image-producing methods (CT*, MR*)**.
>
> [English Translation of Siebels at p. 6, lines 10-18; emphasis added in bold.]

Like Coates, Brantigan teaches at col. 3, lines 9-12 that "The **implants** are **preferably** made of **radiolucent** material such as **carbon fiber reinforced polymers** known commercially as 'Peek' (polyetheretherketone) or 'ultrapeek' (polyether ketone, ether ketone, ketone)." Thus, the implants of Coates and Brantigan each have the same advantage of being radiolucent. Thus, the radiolucence of cortical bone of Coates offers no motivation to substitute over the already radiolucent polymers of Siebels.

Further, Coates' arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), or similar carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit I : from www.matweb.com at page 2, line 10 "Flexural modulus".] These fiber-reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness of cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. [These arguments apply with equal force regarding the carbon fiber reinforced plastic of Siebels in Section III supra.] Thus, the fiber-reinforced plastics of Brantigan (and Coates) do not have the disadvantage of "stress shielding" that is associated with metals. Moreover, they have the same flexibility modulus as cortical bone. Thus, the advantageous property, lack of stress shielding, of cortical bone over metal is not an advantageous property over the fiber-reinforced polymers of Siebels. In fact, Siebels teaches that the fiber-reinforced polymers of the implants of his invention impart "**optimal rigidity and strength**":

> The disk-shaped implant is **preferably** made of **fiber-reinforced plastic [FRP]**. In accordance with a **preferred embodiment** of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

By the word "**optimal**", Siebels means that his materials are the best for strength (due to fiber orientation) and **rigidity**. Coates does not address this teaching in Siebels. Thus, Siebels teaches that the fiber-reinforced polymers of his invention have at least two advantages relative to the single piece cortical bone implants of Coates: "manufactured in an **extraordinarily easy way** . . . **optimal rigidity** and **strength** to the implant."

While the implant of Coates, which is made of Cortical bone, is stated to offer the advantage of remodeling and fusing with the patient's own vertebrae, it is well known in the art that cortical bone is so dense that it fuses poorly. It is not osteoconductive such that cells and vasculature have a difficult time entering the cortical bone to effect remodeling. See . Coates teaches the need to use "bone morphogenic protein" to induce remodeling. [Coates at col. 6, lines 19-20.] The prior art teaches that central cavity of an implant, such as a metal implant, is packed with cancellous chips or a bone paste that is osteoconductive and is readily remodeled so as to fuse with the adjacent vertebrae while the support member maintains support. Similarly, the central cavity of the polymer-reinforced implant of Siebels (or even the bone of Coates) can also be packed with this osteoconductive material (See Fig. 1 of Siebels) to allow a similar fusion that is obtained in Coates. Thus, Coates offers very little in the way of advantage over Siebels and the knowledge already in the art. Moreover, given Coates admitted "**extreme difficulty**" in producing a **single** piece cortical bone implant, versus the "**extraordinarily easy way**" of

making the fiber-reinforced plastic implants of Siebels, one skilled in the art would not have been motivated to use the "extreme[ly] difficult" cortical bone of Coates to make even more difficult cortical bone implants from multiple tiny machined pieces of cortical bone that need to be assembled together and retain the strength and properties. For all these reason, one skilled in the art would not have been motivated by "superior properties in vivo" (because there is no showing of a plurality of "superior properties") and because and minor superiority in a single property is more than offset by the relative ease in manufacturing with FRP versus the admitted difficulty with cortical bone.

For this reason also, the combination of Siebels over Coates would have failed to render obvious claims 26-34 and 61-62 of the Applicants' invention at the time that the Applicants' invention was made.

SUMMARY

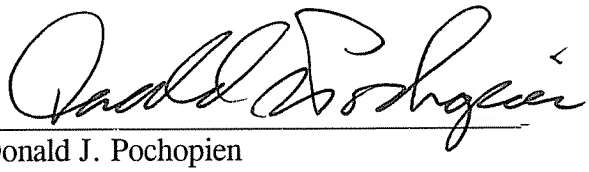
Claims 26-34 and 61-62 are pending and subject to rejection.

In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-34 under 35 U.S.C. § 102 (b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. In view of the evidence, arguments and/or amendments herein, the rejection of claims 26-27, 31-34 and 61-62 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis) has been rebutted and/or rendered moot. Finally, in view of the evidence and arguments herein, all bases for rejection of claims 26-34 and 61-62 under 35 USC § 103(a) over Siebels and Coates have been rebutted.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

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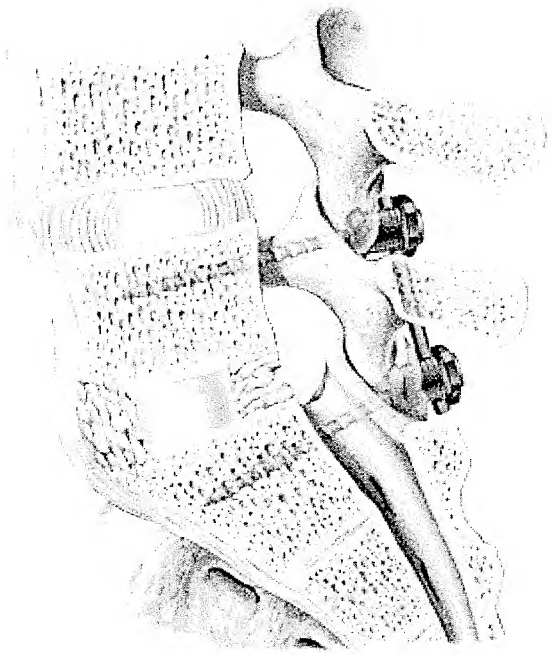

A basic component of any spinal fusion is the bone graft. Bone grafting is used for many types of orthopedic procedures that require bone to heal. Bone grafting is used in two main ways during orthopedic procedures: 1) to stimulate the bone to heal, and 2) to provide support to the skeleton by filling in gaps between two bones.

The most common use of bone graft is to stimulate the healing of bone. The bone graft is used similar to "fertilizer" that stimulates the bone to heal and speeds up the process. When bone tissue is crushed into powder and placed around a fracture or a fusion site, there are chemicals in the bone that stimulate the bone to heal. If the bone is taken from the person's own body, there may also be living bone cells (called osteocytes) that survive being transferred to the new location and continue to go about their business of making new bone. Even bone taken from someone else will stimulate bone to heal. Although, bone taken from the same person may be better because of the possibility of the bone graft having remaining live bone cells during the transfer.

The second way that bone graft is used is for structure. Rather than crush the bone into fine pieces, larger pieces of bone are used to fill a gap between two bones. For example, if the surgeon removes a vertebra or disc, and has a gap to fill, he may place a chunk of bone graft into the space. Because bone is rigid, it will hold the bones apart while the body grows to the chunk of bone graft at either end. Over time, the entire piece of bone that was grafted will be "remodeled" and replaced by the body with new bone. How long this takes depends on how big a piece of bone was used. It

is a slow process that may take years.

Bone taken from your own body is called autograft. Bone graft taken from someone else is called allograft. Allograft is usually removed from organ donors and placed in bone banks. The bone bank follows procedures intended to sterilize the bone graft and performs tests on the bone for diseases such as hepatitis and AIDS (just like a blood bank). The bone bank then sells the allograft to the hospital that performs your surgery. The cost will show up on your hospital bill.

An allograft can come from many types of bones in many different forms, but because it is not taken from the patient, it does not contain any living cells and has fewer chemicals to stimulate growth of new bone. The disadvantage of an allograft is that it does not always heal as well or as quickly as an autograft. However, a bone-growing protein can be added to the site to make up for the lack in the bone graft. The advantage is that the patient does not have to donate the bone graft, so the surgery is shorter, and there may be less postoperative pain. The allograft also carries a risk of transferring infectious diseases, although it is rigidly tested.

Allograft is very useful when the operation will require more bone graft than your own body can supply. Some major spine fusions need a lot of bone graft and the surgeon may mix allograft with autograft. Some surgeries need large pieces of structural bone graft and it would cause a problem in the area where the bone was removed if it were taken from your own body.

There has been a great deal of research to design bone graft substitutes, chemicals, and devices that can stimulate the bone to fuse and grow together. Electrical current has been known for some time to stimulate bone to grow, so many surgeons use electrical stimulation devices during the first weeks of surgery to speed up a fusion. Artificial bone graft materials have been developed. Sea Coral, harvested from oceans, has actually been used as the basis for a structural bone replacement very successfully.

Demineralized Bone Matrix (DBM) is a type of allograft that is developed from cadaver bones in a bone bank. The bone has the calcium removed and can be turned into a putty, sheet, or gel. The material can then be added to a graft site to improve the fusion. Bone Morphogenic Protein (BMP) is an additional material that has been developed recently. BMP is a chemical that is added to bone graft and enhances bone growth when it is added to a fusion site.

Your surgeon will try to promote and speed the healing of your spinal fusion in a number of ways. The most common approach is to use your own bone whenever possible - it seems to be best at getting bone to heal. Allograft may be used to reduce your risks of problems with taking the bone graft from your body when more bone graft is needed than your body can supply.

Be sure to discuss the different options with your surgeon.

EXHIBIT
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SECOND COLLEGE EDITION

WEBSTER'S NEW WORLD DICTIONARY

OF THE AMERICAN LANGUAGE

DAVID B. GURALNIK, *Editor in Chief*

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optic axis in a crystal not having the same properties in all directions with regard to light, a direction along which there is no apparent double refraction since both components of the light ray have the same velocity
optic disk *same as* BLIND SPOT (sense 1)
op·ti·cian (äp tish′ən) *n.* [Fr. *opticien*] a person who makes or deals in optical instruments, esp. one who prepares and dispenses eyeglasses
optic nerve either of the second pair of cranial nerves, which connect the retina of the eye with the brain
op·tics (äp′tiks) *n.pl.* [*with sing. v.*] [< OPTIC] the branch of physics dealing with the nature and properties of light and vision
op·ti·mal (äp′tə məl) *adj.* [OPTIM(UM) + -AL] most favorable or desirable; best; optimum —**op′ti·mal·ly** *adv.*
op·ti·mism (-miz′m) *n.* [Fr. *optimisme* < L. *optimus*, best (see OPTIMUM)] 1. *Philos. a*) the doctrine held by Leibniz and others that the existing world is the best possible *b*) the doctrine or belief that good ultimately prevails over evil 2. the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome; practice of looking on the bright side of things —**op′ti·mist** (-mist) *n.* —**op′ti·mis′tic** (-mis′tik), **op′ti·mis′ti·cal** *adj.* —**op′ti·mis′ti·cal·ly** *adv.*
op·ti·mize (-miz′) *vi.* **-mized′**, **-miz′ing** to be given to optimism —*vt.* to make the most of; develop or realize to the utmost extent; obtain the most efficient or optimum use of —**op′ti·mi·za′tion** *n.*
op·ti·mum (-məm) *n.*, *pl.* **-mums**, **-ma** (-mə) [L., neut. of *optimus*, best < *ops*, power, riches: for base see OPUS] 1. the best or most favorable degree, condition, amount, etc. 2. *Biol.* the amount of heat, light, moisture, food, etc. most favorable for growth and reproduction —*adj.* most favorable or desirable; best; optimal
op·tion (äp′shən) *n.* [Fr. < L. *optio* < *optare*, to wish, desire, ult. < IE. base **op-*, to choose, prefer] 1. the act of choosing: choice 2. the power, right, or liberty of choosing 3. something that is or can be chosen; choice 4. the right, acquired for a consideration, to buy, sell, or lease something at a fixed price, sign or renew a contract, etc. within a specified time —☆*vt. Sports* to transfer (a player) to a minor league with the option of recalling him —*SYN.* see CHOICE
op·tion·al (-'l) *adj.* left to one's option, or choice; not compulsory; elective —**op′tion·al·ly** *adv.*
op·to·e·lec·tron·ics (äp′tō i lek′trän′iks) *n.pl.* a branch of electronics involving the use of optical technology —**op′to·e·lec′tron′ic** *adj.*
op·tom·e·ter (äp täm′ə tər) *n.* [see OPTIC & -METER] an instrument for determining error in the refractive power of the eye
☆**op·tom·e·trist** (-trist) *n.* a specialist in optometry
op·tom·e·try (-trē) *n.* [see OPTIC & -METRY] 1. measurement of the range and power of vision 2. the profession of examining the eyes and measuring errors in refraction and of prescribing glasses to correct these defects —**op·to·met·ric** (äp′tə met′rik), **op′to·met′ri·cal** *adj.*
op·u·lent (äp′yə lənt) *adj.* [L. *opulentus* or *opulens* < *ops:* see OPUS] 1. very wealthy or rich 2. characterized by abundance or profusion; luxuriant —*SYN.* see RICH —**op′u·lence**, **op′u·len·cy** *n.* —**op′u·lent·ly** *adv.*
o·pun·ti·a (ō pun′shē ə, -shə) *n.* [ModL. < L. (*herba*) *Opuntia*, (plant) of Opus, city in Locris, Greece] any of a large genus (*Opuntia*) of cactus plants with red, purple, or yellow flowers, pulpy or dry berries, and fleshy, jointed stems, including the prickly pears and chollas
o·pus (ō′pəs) *n.*, *pl.* **o·pe·ra** (ō′pə rə, äp′ər ə), **o′pus·es** [L., a work < IE. **ops* < base **op-*, to work, riches, whence L. *ops*, riches, Sans. *ápas-*, work, OE. *efnan*, to work, do] a work; composition; esp., any of the musical works of a composer numbered in order of composition or publication
o·pus·cule (ō pus′kyōōl) *n.* [Fr. < L. *opusculum*, dim. of *opus:* see prec.] a minor work —**o·pus′cu·lar** *adj.*
-o·py (ō′pē) *same as* -OPIA
☆**o·quas·sa** (ō kwas′ə) *n.* [< *Oquassa* Lake, in Maine] a small trout (*Salvelinus oquassa*) of lakes of W Maine
or[1] (ôr; *unstressed* ər) *conj.* [ME., in form a contr. of *other*, *auther*, either, but actually < OE. *oththe* (in *āther . . . oththe*, either . . . or)] a coordinating conjunction introducing an alternative; specif., *a*) introducing the second of two possibilities [beer *or* wine] *b*) introducing any of the possibilities in a series, but usually used only before the last [apples, (*or*) pears, *or* plums] *c*) introducing a synonymous word or phrase [botany, *or* the science of plants] *d*) introducing the second of two possibilities when the first is introduced by *either* or *whether* [either go *or* stay, whether to go *or* stay] *e*) substituted for *either* as the first correlative ["*or* in the heart *or* in the head"]
or[2] (ôr) *conj., prep.* [ME. < OE. *ār*, var. of *ær*, *ere:* cf. ERE] [Archaic or Dial.] before; ere
or[3] (ôr) *n.* [Fr. < L. *aurum*, gold: for IE. base see EAST] *Heraldry* gold or yellow, represented in engraving by small dots powdered over a plain field
-or (ər; *occas.* ôr) 1. [ME. *-our* < OFr. *-our*, *-or*, *-eur* < L. *-or*, *-ator*] *a n.-forming suffix meaning* a person or thing that [*inventor, objector*] 2. [ME. *-our* < OFr. < L. *-or*] *a n.-forming suffix meaning* quality or condition [*horror, error*]: in Brit. usage, often **-our**
‡**o·ra** (ôr′ə) *n. pl. of* OS[2]
or·ach, or·ache (ôr′əch, är′-) *n.* [ME. *orage* < Anglo-Fr. *orache* < OFr. *arroche* < VL. **atrapica* (for L. *atriplex*) < Gr. *atraphaxys*] any of a genus (*Atriplex*) of plants of the goosefoot family, widespread in salty or alkaline areas, having usually silvery foliage and small green flowers; esp., **garden orach** (*Atriplex hortensis*), cultivated as a potherb, chiefly in France
or·a·cle (ôr′ə k'l, är′-) *n.* [ME. < OFr. < L. *oraculum*, divine announcement, oracle < *orare*, to speak, pray, beseech < *os* (gen. *oris*), the mouth: see ORAL] 1. among the ancient Greeks and Romans, *a*) the place where, or medium by which, deities were consulted *b*) the revelation or response of a medium or priest 2. *a*) any person or agency believed to be in communication with a deity *b*) any person of great knowledge or wisdom *c*) opinion or statements of any such oracle 3. the holy of holies of the ancient Jewish Temple: I Kings 6:16, 19–23
o·rac·u·lar (ô rak′yoo lər) *adj.* 1. of, or having the nature of, an oracle 2. like an oracle; wise, prophetic, mysterious, etc. —**o·rac′u·lar′i·ty** (-yə lar′ə tē) *n.* —**o·rac′u·lar·ly** *adv.*
o·rad (ôr′ad) *adv.* [< L. *os* (gen. *oris*), the mouth + -AD[2]] toward the mouth or oral region
O·ra·dea (ô räd′yä) city in NW Romania, near the Hungarian border: pop. 112,000
o·ral (ôr′əl) *adj.* [< L. *os* (gen. *oris*), the mouth < IE. base **ōus-*, mouth, edge, whence Sans. *ā-ḥ*, mouth, ON. *ōss*, mouth of a stream] 1. uttered by the mouth; spoken 2. of speech; using speech 3. of, at, or near the mouth 4. *Phonet.* having mouth resonance only: distinguished from NASAL 5. *Psychoanalysis a*) designating or of the earliest stage of psychosexual development in which interest centers around sucking, feeding, and biting *b*) designating or of such traits in the adult as friendliness, generosity, and optimism or aggressiveness and pessimism, regarded as unconscious psychic residues of that stage: cf. ANAL, GENITAL 6. *Zool.* on or of the same side as the mouth —☆*n.* an examination that is oral and not written, as in a college —**o′ral·ly** *adv.*
SYN.—**oral** refers to that which is spoken, as distinguished from that which is written or otherwise communicated [an *oral* promise, request, etc.]; **verbal**, though sometimes synonymous with **oral**, in strict discrimination refers to anything using words, either written or oral, to communicate an idea or feeling [a *verbal* image, caricature, etc.]
oral history 1. historical data consisting of personal recollections, usually in the form of a tape-recorded interview 2. the gathering and preservation of such data
o·ral·ism (ôr′əl iz′m) *n.* the theory or practice of teaching the deaf to read lips and to speak —**o′ral·ist** *adj., n.*
O·ran (ō ran′; *Fr.* ô rän′) seaport in N Algeria, on the Mediterranean: pop. 430,000
o·rang (ô raŋ′, ə-) *n. same as* ORANGUTAN
Or·ange[1] (ôr′inj, är′-) ruling family of the Netherlands: see NASSAU —*adj.* of or having to do with Orangemen
Or·ange[2] (ôr′inj, är′-; *also, for 3 & 4, Fr.* ô ränzh′) 1. [prob. after the *orange* groves there] city in SW Calif.: suburb of Los Angeles: pop. 92,000 2. river in South Africa, flowing from NE Lesotho west into the Atlantic: c. 1,300 mi. 3. former principality of W Europe, now in SE France 4. city in SE France: pop. 21,000
or·ange (ôr′inj, är′-) *n.* [ME. < OFr. *orenge* < Pr. *auranja* (with sp. influenced by L. *aurum*, gold & loss of initial *n* through faulty separation of art. *un*) < Sp. *naranja* < Ar. *nāranj* < Per. *nārang* < Sans. *naranga*, prob. akin to Tamil *naṟu*, fragrant] 1. a reddish-yellow, round, edible citrus fruit, with a sweet, juicy pulp 2. any of various evergreen trees (genus *Citrus*) of the rue family producing this fruit, having white, fragrant blossoms, often carried by brides, and hard, yellow wood 3. any of several plants or fruits resembling the orange 4. reddish yellow —*adj.* 1. reddish-yellow 2. made with or from orange 3. having a flavor like that of oranges —**or′ang·y** (-in jē) *adj.*
or·ange·ade (-ād′) *n.* [Fr.: see ORANGE & -ADE] a drink made of orange juice and water, usually sweetened
Orange Free State province of South Africa, west of Lesotho: formerly a Boer republic (1854–1900) & then a Brit. colony (**Orange River Colony**, 1900–10): 49,866 sq. mi.; pop. 1,387,000; cap. Bloemfontein
☆**orange hawkweed** *same as* DEVIL'S PAINTBRUSH
Or·ange·ism (ôr′inj iz′m, är′-) *n.* the principles and practices of the Orangemen
Or·ange·man (-mən) *n.*, *pl.* **-men** (-mən) [after the Prince of *Orange*, later WILLIAM III] a member of a secret Protestant society organized in N Ireland (1795)
orange pekoe a black tea of Ceylon and India: see PEKOE
or·ange·ry (ôr′inj rē, är′-) *n.*, *pl.* **-ries** [Fr. *orangerie* < *oranger*, orange tree < *orange*] a hothouse or other sheltered place for growing orange trees in cooler climates
☆**orange stick** a pointed stick, orig. of orangewood, used in manicuring

EXHIBIT
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US005192327A

United States Patent [19]

Brantigan

[11] Patent Number: 5,192,327

[45] Date of Patent: Mar. 9, 1993

[54] **SURGICAL PROSTHETIC IMPLANT FOR VERTEBRAE**

[76] Inventor: **John W. Brantigan**, 328 Overlook Brook Ct., Chagrin Falls, Ohio 44022

[21] Appl. No.: **673,474**

[22] Filed: **Mar. 22, 1991**

[51] **Int. Cl.**[5] **A61F 2/44**

[52] **U.S. Cl.** **623/17**; 606/60; 606/61

[58] **Field of Search** 623/17; 606/60, 61

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Primary Examiner—Randall L. Green
Assistant Examiner—Dinh Nguyen

[57] **ABSTRACT**

Surgical prosthetic modular implants used singularly or stacked together are provided to support and fuse together adjacent vertebrae or to totally or partially replace one or more vertebrae in a vertebral column. The implants are rigid annular plugs, dimensionally similar to normal vertebral bodies, have simplified oval or hemi-oval shapes with ridged faces to engage adjacent vertebral bodies to resist displacement and allow bone ingrowth and fusion and to interdigitate with the ridges of an adjacent plug for modular stacking to allow variability of ultimate implant height. The implants can be provided in sets of different thicknesses and are internally grooved to receive an upstanding connecting bar to bind together the individual stacked implants into a stable unit. The annular implants have ample spaces to allow ingrowth of blood capillaries and packing of bone graft and are preferably made of a radiolucent material, preferably biocompatible carbon fiber reinforced polymers or are alternately made of traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium.

14 Claims, 3 Drawing Sheets

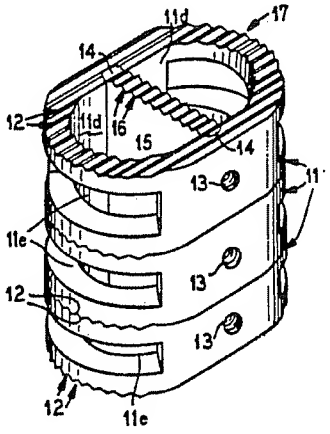


FIG. 1

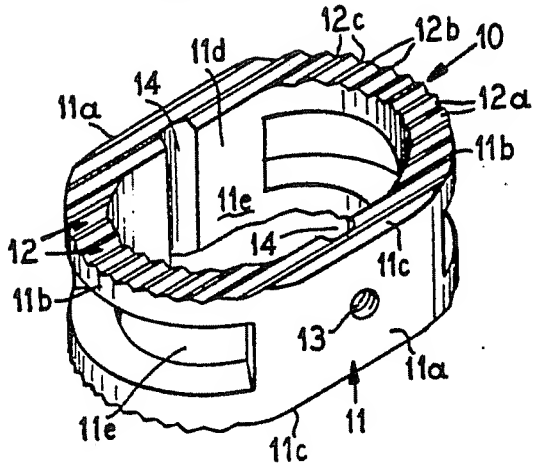


FIG. 2

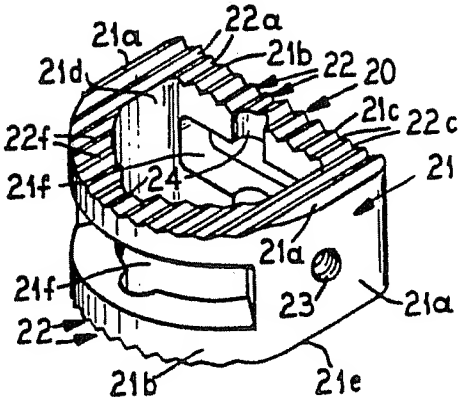


FIG. 3

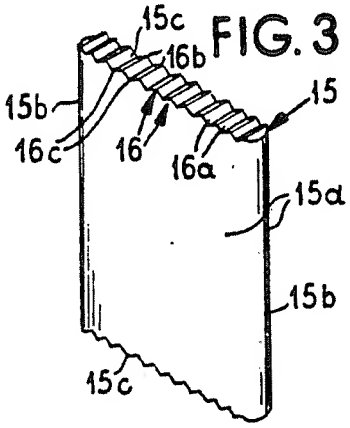


FIG. 4

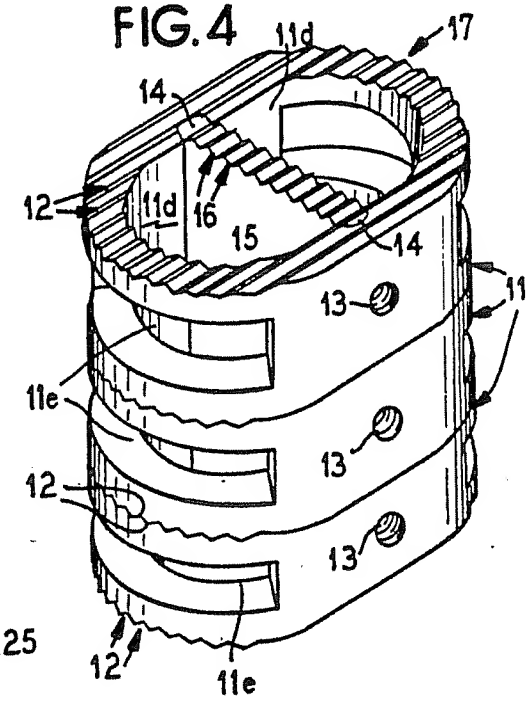


FIG. 5

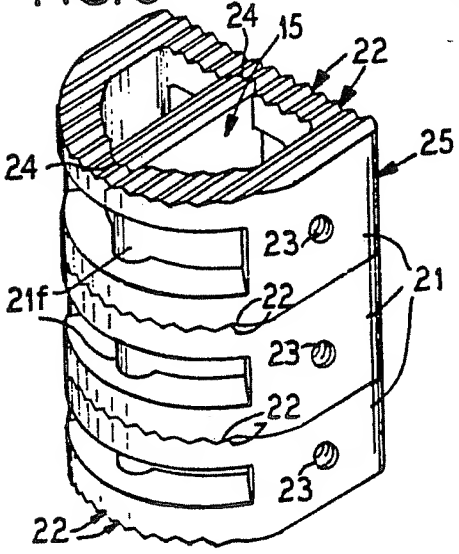


FIG. 6

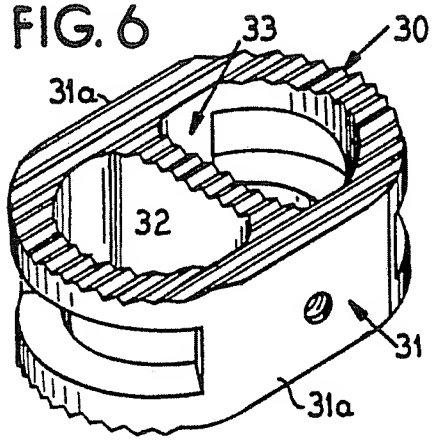


FIG. 8

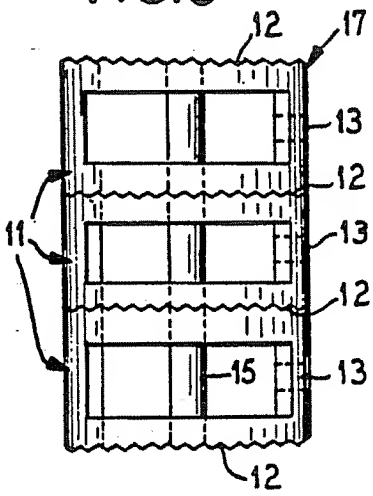


FIG. 7

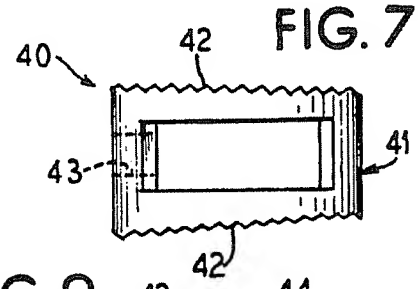


FIG. 9

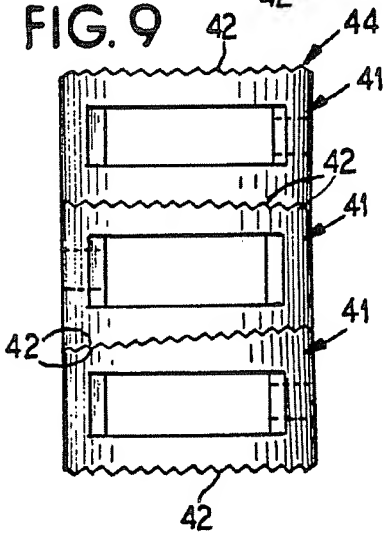


FIG. 10

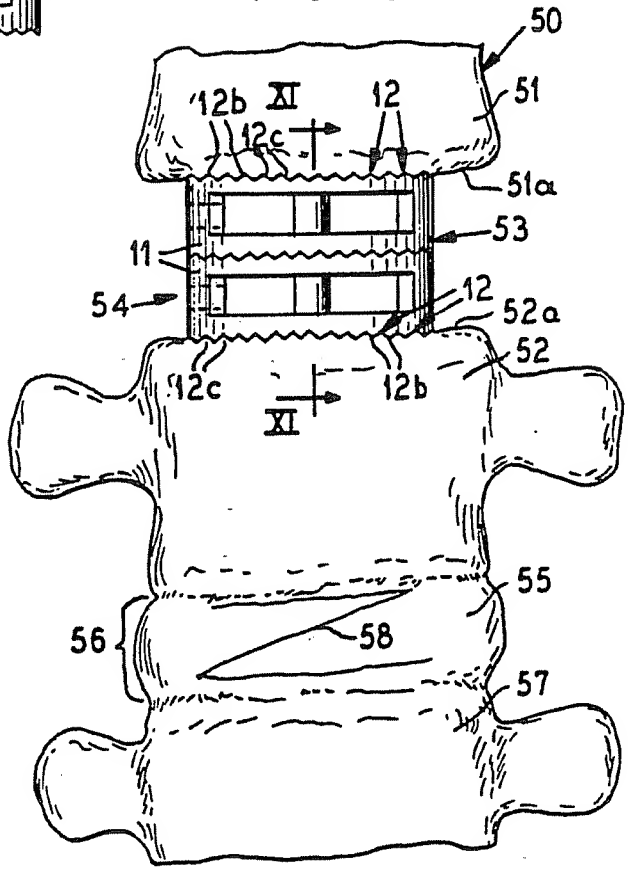


FIG. 11

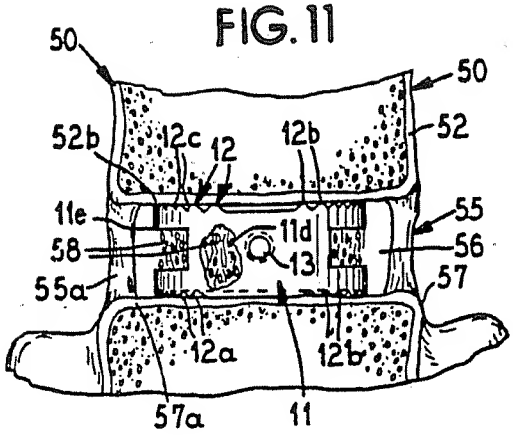


FIG. 12

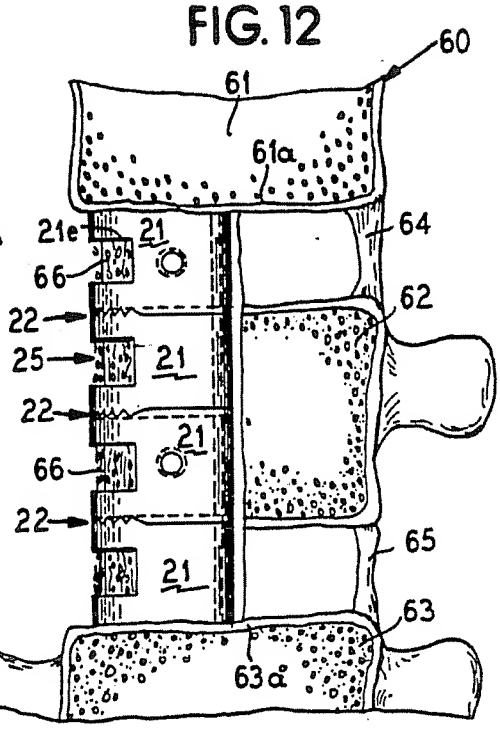


FIG. 15

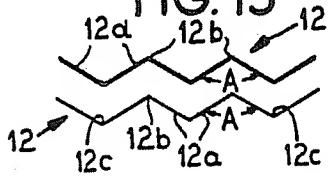


FIG. 13

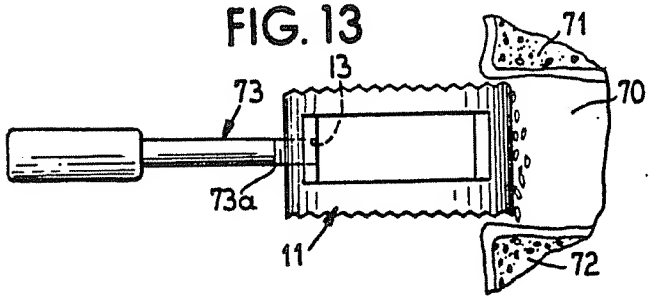
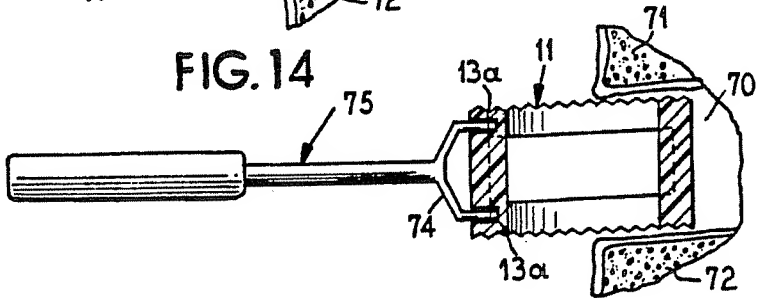


FIG. 14



SURGICAL PROSTHETIC IMPLANT FOR VERTEBRAE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to inert rigid vertebral prosthetic devices and methods for implanting the devices between adjacent vertebrae to treat or prevent back or neck pain in patients with ruptured or degenerated intervertebral discs and for replacing vertebral bodies damaged by fracture, tumor or degenerative process. Specifically, the invention deals with ring-like prosthetic plugs or discs used singly or stacked together between vertebrae to form support sturts in the spinal column and having rigid surfaces facilitating anchoring and providing valleys for bone ingrowth from adjoining vertebrae. The rings are bottomed on the opposing end faces of adjoining vertebrae, are preferably oval shaped with medial-lateral and anterior-posterior dimensions in the same ratio as normal vertebral bodies, are supplied in different heights to be used individually to replace a single damaged intervertebral disc, have ridges to bite into the vertebrae or to interdigitate to be securely stacked together to the exact height required at the time of surgery, have slots and hollow areas for packing bone graft material, tool receiving means, and are preferably radiolucent to allow visualization of the bone healing postoperatively.

2. Description of the Prior Art

While many types of vertebral prosthetic devices have been proposed, the success ratio has been very low and the surgical procedures have been very complicated and traumatic to the patient. The surgical implant devices and methods covered in my U.S. Pat. Nos. 4,743,256; 4,834,757 and 4,878,915 have greatly improved the success rate and have simplified the surgical techniques in interbody vertebral fusion. In the procedures covered by these patents, biologically acceptable but completely inert strut plugs are bottomed in channels or grooves of adjoining vertebrae and receive bone ingrowth which quickly fuses the structure to the bone and forms a living bone bridge across the fusion area.

The present invention now further improves this art of interbody fusion without cutting grooves or channels in the vertebrae and is especially well suited for anterior cervical and lumbar fusion. The invention provides ring-like prosthesis plugs or discs bottomed on end faces of adjoining vertebrae and constructed and arranged so that they can be used singly or stacked plurally to accommodate individual surgical requirements. The rings can replace excised discs and vertebrae and can also be mounted inside the fibrous disc column connecting adjoining vertebrae. The annular units are preferably oval or partial oval shaped preferably hemi-oval, to conform with vertebral disc shapes, have ridged or peaked surfaces for biting into the vertebrae on which they are seated and for receiving bone ingrowth in valleys between the peaks. When stacked, an interior connecting bar can be provided to lock the components in fixed relation and cooperate with interfitting ridges.

SUMMARY OF THE INVENTION

According to this invention, biologically acceptable, but inert rigid annular prosthesis units are provided to support and fuse with adjacent vertebrae in both the cervical, thoracic spine and lumbar portions of a human vertebral column. These ring-like prosthetic devices are bottomed on the hard bone faces or end plates of adjacent vertebrae and are generally oval shaped to conform with the general outline perimeter of the vertebrae. They are also provided in partial (preferably hemi-oval) annular shape to accommodate those surgical procedures where only a portion of the vertebrae or disc is damaged. Two such hemi-oval rings can be used in the posterior lumbar area in side-by-side relation since the dural sac and nerve roots must be retracted to each side in turn as the implant is placed on the opposite side. In an anterior fusion since the entire front of the disc space is exposed, a single piece implant can be used making the oval an advantage in this area.

The periphery of the oval ring is grooved to accommodate ingrowth of blood capillaries and the open central portion of the ring is preferably packed with bone graft material to facilitate bone ingrowth. Bone graft can also be packed in the grooves.

Each of the oval implants is sized to match the height of an average disc and thus, can vary from 10 to 15 mm for the lumbar area and from 7–11 mm for the cervical area.

The oval shape simplifies the surgical procedure since it can be rotated or reversed and still fit the vertebrae. Further, the device stretches the disc tissue creating a tension which will cause the vertebrae to tightly grip the ring on which it is bottomed. If the disc columnar tissue is preserved, a cut, preferably "Z"-shaped, can be made in the columnar fibrous tissue, the interior pulpus material of the disc removed, and the ring implant inserted through the cut to be bottomed on the adjoining vertebrae and surrounded by the disc tissue.

To accommodate a myriad of different heights between vertebrae on which the prosthesis ring is to be bottomed, the rings can be supplied in sets of different heights to be stacked to the exact height required for a particular surgical implant. For example, in the cervical spine, cervical corpectomy is often required for cervical myelopathies in which large bone spurs cause spinal cord pressure. An average grafting height is 30 mm after corpectomy and this can be achieved by stacking, for example, three 10 mm high oval implants.

In the treatment of thora columbar fractures, hemicorpectomy is often done followed by grafting. Placement of stacked hemi-oval implants in the hemi-corpectomy area provides solid structural weight bearing. The re-sected vertebral bone is packed into the implant so that harvesting of additional bone grafting can be avoided.

In the treatment of vertebral tumors, the stacked oval implants can achieve solid bony fusion across the entire re-sected area providing a permanent mechanically secure repair with living tissue.

The invention now provides vertebral prosthetic implant devices suitable for anterior, posterior or lateral placement in any area of the spine requiring replacement of disc or vertebral body. Since the implants are intended to bottom out on adjacent vertebral end faces, which preferably have been prepared by flattening with a burr drill, removing cartilaginous material and stretching the annular fibrosis so that the vertebrae can tightly grip the plug, the plugs can be inserted either anteriorly, posteriorly or laterally into the vertebral column while mounted on the end of an insertion tool.

The ring devices have ridged surfaces providing multiple purposes of gripping the vertebrae to resist expul-

sion, forming valleys to facilitate bone ingrowth, and to matching interdigitate with each other for stacking.

An upstanding longitudinal connecting member fits in interior grooves in the ring and cooperates with the ridges to prevent separation of stacked implants in every direction except in longitudinal height. Since the implants are placed in compression between the vertebral bodies, they cannot come apart after implantation.

The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). Alternately, polycarbonate, polyprophylene, polyethelyene and polysulfone type plastics material filled with glass or carbon fibers can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.

Preferred best mode embodiments of the invention are illustrated in the attached drawings in which:

FIG. 1 is a top and side perspective view of a full oval prosthetic device according to this invention;

FIG. 2 is a top and side perspective view of a hemi-oval prosthetic device of this invention;

FIG. 3 is a top and side perspective view of a connecting bar fitting the illustrated grooves in the devices of FIGS. 1 and 2 to hold a plurality of the devices in stacked relation;

FIG. 4 is a top and side perspective view of a stack of the devices of FIG. 1 with the connecting bar of FIG. 3 in place;

FIG. 5 is a top and side perspective view of a stack of the devices of FIG. 2 with a connecting bar like FIG. 3 in place;

FIG. 6 is a view similar to FIG. 1 but illustrating a modified device with an integral cross bar;

FIG. 7 is a side view showing a tapered device of this invention;

FIG. 8 is a side view of the stack of devices of FIG. 4 showing how the ridges interdigitate when stacked;

FIG. 9 is a view similar to FIG. 8 but showing a stack of tapered devices of FIG. 7 with the center device rotated 180° to form a vertical stack with end faces tapered in the same direction.

FIG. 10 is an elevational view of a portion of a vertebrae column showing a two stack assembly in an excised disc space between adjacent vertebrae and the manner in which a disc can be cut to receive a device of this invention.

FIG. 11 is a sectional view along the line XI—XI of FIG. 10;

FIG. 12 is a longitudinal view of a portion of a vertebral column, with parts in section and broken away to show the manner in which a stack of the devices is used to replace partially damaged discs and an intermediate vertebrae portion;

FIG. 13 is side diagrammatic view showing the insertion of a device of this invention in a disc space with the aid of a mounting tool.

FIG. 14 is a view similar to FIG. 13 illustrating the manner in which a fork-like tool can have tines mounted in a pair of holes in the device.

FIG. 15 is a line diagram illustrating the manner in which the ridges of the plugs have side walls diverging at the same angles from the peaks to provide interdigitating or complimentary mating or nesting projections.

As shown on the drawings:

In FIG. 1, the reference numeral 10 designates generally a vertebrae prosthesis device of this invention composed of rigid biologically acceptable and inactive material, preferably a radiolucent plastics material, inert metal and the like as described above. The device 10 is an oval ring plug 11 generally shaped and sized to conform with the disc space between adjoining vertebrae in a vertebral column. The plug 11 has opposed sides 11*a* and ends 11*b*, flat, ridged top and bottom faces 11*c* and a central upstanding aperture 11*d* therethrough. The ends 11*b* have relatively wide and long horizontal peripheral slots 11*e* therethrough preferably extending into the sides 11*a* and communicating with the central aperture 11*d*.

Ridges 12 are formed longitudinally across the end faces 11*c*. These ridges 12 have inclined side walls 12*a* merging at sharp peaks 12*b* and provide valleys 12*c* between the side walls. The valleys 12*c* open at the ends 11*b* of the oval ring plug 11.

One side wall 11*a* of the plug 11 has an internally threaded hole 13 extending partially through the wall for receiving a mounting tool as hereinafter described.

The interior faces of the side walls 11*a* also have upstanding open ended vertical grooves 14 preferably of fragmental cylindrical configuration. These grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3. This bar 15 has flat side faces 15*a*, rounded side edges 15*b* to snugly fit the grooves 14 and top and bottom end edges 15*c* which are provided with ridges 16 that conform with the ridges 12 of the plug 10. Thus, these ridges 16 have oppositely inclined sides 16*a* converging to peaks 16*b* and providing valleys 16*c* therebetween. The peaks and valleys of the ridges on the ends of the connecting bar 15 are aligned with the peaks and valleys of the ridges on the top and bottom faces 11*c* of the plug 11 when the bar is seated in place in the grooves 14.

The connecting bar 15 has a height conforming with the total height of a stack 17 of plugs 11 shown in FIG. 4 or with only a single plug 11 if a stack of plugs is not necessary. As shown in FIG. 4 three plugs 11 are stacked together with the ridges 12 of the intermediate plug nested in and interdigitating with the ridges of top and bottom plugs. These ridges interfit to provide a stable stack and the connecting bar 15 seated in the aligned grooves 14 of the three plugs will prevent shifting of the stack. The end faces of the bars 15 will then have their ridges 16 aligned with the ridges 12 in the exposed end faces of the top and bottom plugs 11.

The central aperture 11*d* of each plug 11 is separated by the bar 15 into two side-by-side chambers which are easily packed with bone graft material to expedite the fusion of the prosthesis device in the spinal column. In addition, the slots 11*e* in the ends 11*b* of the plugs can receive bone graft material and also provide free spaces for blood flow to speed up the fusion process.

A modified hemi-oval device 20 is illustrated in FIG. 2 for usage in partial corpectomy operations and also for use in spaced side-by-side relation when an intermediate nerve space is needed. The device 20 is a one-piece plastics material or metal plug 21 of generally hemi-oval shape with opposed side walls 21*a*, a rounded oval end wall 21*b*, a flat opposite end wall 21*c* and a central aperture 21*d*. The top and bottom faces 21*e* of the plug 21 are ridged in the same manner as the plug 11 thus providing longitudinal ridges 22 with inclined side walls 22*a*, peaks 22*b* and valleys 22*c*. The end walls 21*b* and 21*c* have the same slots 21*f* as the slots 11*e* of the plug 11

and an end wall 21*a* has the same tool receiving recess 23 as the plug 11.

Internal grooves 24 are provided in the inner faces of the end walls 21*b* and 21*c* of the plug 21 to receive a connecting bar such as 15. This bar however will divide the central aperture of the plug 21 in a longitudinal instead of a transverse direction as illustrated for the plugs 11.

As shown in FIG. 5 the plugs 21 form a stack 25, in the same manner as the plugs 11 in the stack 17 of FIG. 4 with the same type of connecting bar 15.

The plugs 11 and 21 of FIGS. 1 to 5 may vary in thickness or height to suit conditions and in the stacks of FIGS. 4 and 5, plugs of different thicknesses or heights can be stacked together to provide the desired overall height for each operation. Sets of these plugs may thus be supplied so that the surgeon can easily end up with a stack of the required height to fit the patient. The lengths or heights of the connecting bars 15 can also be varied to suit conditions or can be ground down at the time of the operation to match the stack.

The ridges on the exposed end faces of the stacks of plugs will bottom on the hard end faces or end plates of adjacent vertebrae and the apices or peaks 21*b* and 22*g* of these ridges will firmly engage and bite into these faces to prevent slippage. In addition, the valleys 12*c* and 22*c* between the ridges serve as gaps or troughs to freely receive bone ingrowth from the adjacent vertebrae.

The individual plugs or the stack of plugs can be introduced anteriorly, laterally or posteriorly depending upon conditions and the tool receiving recesses 13 and 23 of the plugs 11 and 21 can thus be positioned to meet the particular type of insertion into the vertebral column.

Instead of providing a separate bar or plate 15, as shown in FIG. 6, a modified device 30 of this invention is a plug 31 of the same oval shape as the plug 11 of FIGS. 1 and 4 but the reinforcing bar 32 of this plug is integral with its side walls 31*a*. The hollow interior 23 of the plug 31 is thus bisected by an integral internal partition 32 forming a pair of side-by-side apertures through the plug adapted to receive bone graft material.

A plug similar to 30 can also be provided in a hemi-oval shape. The plugs with the integral dividing bar are preferably used singly but also can be stacked and interdigitated by their ridges.

The plugs 11, 21 and 31 of FIGS. 1, 2 and 6 are uniform in thickness or height across their length.

In a further modified device 40 shown in FIG. 7, the plug 41 is tapered to be higher or thicker at its anterior end than at its posterior end. The plug 41 has ridged top and bottom faces 42, the same as the plugs of FIGS. 1–6 and a tool receiving recess 43 is provided in its higher or trailing end. By way of an example, the trailing end could be 12 mm in height while the leading end reduced to 9 mm in height.

In the stacking of plugs, each of which have uniform height or thickness such as shown at 11, 21, and 31, the holes for the mounting tool can all be aligned on one side of the stack as illustrated in FIG. 8 but, as shown in FIG. 9, the forming of a stack 44 of tapered plugs 41 requires displacement of the central or middle plug 180° from the end plugs in order that the stack will have a vertical column contour. The ridged faces 42 of the tapered plugs 41 will interdigitate and the exposed end faces of these ridges will be inclined or tapered to suit surgical application in spaces where the adjacent vertebrae are wider at one end than at the other. The use of the tapered plugs eliminates some of the grinding of the end faces of the vertebrae that may be needed for a good matching of the ridges with the vertebrae faces.

As shown in FIG. 10, a portion of a human vertebral column 50 has adjoining vertebrae 51 and 52 fused together by a two-unit stack 53 composed of the plugs 11 illustrated in detail in FIGS. 1, 4 and 8. This stack 53 fits the disc space 54 between the vertebrae 51 and 52 and the top ridges 12 of the stack are bottomed on and bite into the bottom face or hard end plate of the upper vertebrae 51 while the bottom ridges 12 of the stack are bottomed on and bite into the upper face or hand end plate 52*a*. The peaks 12*b* of the ridges 12 firmly anchor the stack to the vertebrae but do not penetrate through the hard faces 51*a* and 52*a* of the vertebrae. The valleys 12*c* are exposed to the vertebrae faces and receive bone ingrowth from the vertebrae during the post-operative fusion.

As shown all of the disc has been removed from the disc space 54 and the stack 53 maintains the disc space at its normal height.

As shown in FIGS. 10 and 11, a vertebral disc 55 fills the disc space 56 between the vertebrae 52 and a lower vertebrae 57 of the vertebral column 50. A Z-shaped cut 58 through the tubular fibrous portion of the disc 55 provides access to the interior pulpus portion of the disc permitting its removal to receive a single plug 11 forming a rigid strut inside of the column of disc fibers 55*a* which remain attached to the bottom face 52*b* of the upper vertebrae 52 and the top face 57*a* of the lower vertebrae 57. As illustrated, the peaks 12*b* of the ridges 12 on the top and bottom faces of the plug 11 bite into the faces 52*b* and 57*a* and the valleys 12*c* between the peaks are openly exposed to these faces of the vertebrae.

As better shown in FIG. 11, the hollow interior 11*d* and the slots 11*e* of the plug 11 are packed with bone graft material 58 which can be conveniently harvested from the iliac crests of the patient's pelvic bone.

FIG. 12 illustrates a cervical portion 60 of a human vertebral column having an upper vertebrae 61, a middle vertebrae 62 and a bottom vertebrae 63 with a stack 25 like FIG. 5 but composed of four plugs 21 implanted to support the column. As shown, the top and bottom vertebrae 63 remain intact while the middle vertebrae 62 has been partially excised. The four hemi-oval plug units 21 are interdigitated together through their ridges 22 and a bar 15 such as shown in FIG. 5 can hold the units in an upright column. Discs 64 and 65 have also been partially excised to receive the stack 25 but their remaining tissue is anchored to their adjacent vertebrae.

The bottom face 61*a* of the upper vertebrae 61 and the top face 63*a* of the bottom vertebrae 63 are partially penetrated by the peaks of the ridges of the top and bottom plugs 21 to function as described above. Also, the hollow interiors of the hemi-oval plugs 21 and their slots 21*e* are filled with bone graft material 66.

During surgery, the spinal column is stretched to regain any lost disc space caused by herniation of the discs. This stretches the remaining disc tissue and as illustrated in FIGS. 13 and 14, the plugs of this invention such as the plugs 11 or a stack of the plugs, are inserted into the opened up disc space such as 70 between adjacent vertebrae 71 and 72, either anteriorly, laterally or posteriorly while mounted on a tool 73 having a single end 73*a* threaded into the internally threaded hole 13 of the plug 11 as illustrated in FIG. 13.

Alternately, the plug **11**, as illustrated in FIG. **14** may have a pair of side-by-side holes **13***a* receiving the tine end **74** of a modified tool **75**.

Tools such as **73** and **75** may also be replaced with other gripping tools which do not require amounting apertures in the end faces of the plugs.

As better shown in the line diagram of FIG. **15** the ridged faces such as **12** of twos stacked plugs such as **11** of FIG. **1** have equally inclined side walls **12***a* diverging from sharp peaks **12***b* at a relatively wide angle A to prevent formation of thin narrow fingers or teeth that could break off and narrow valleys that could block bone ingrowth. An angle of at least 30°–45° is preferred to provide wide ridges and open valleys.

From the above descriptions, it will understood that this invention now advances the art of vertebral column surgery and provides prosthetic devices used singly or stacked to desired heights, which fit the disc spaces between adjacent vertebrae, bottom on and bite into the vertebrae faces without penetrating the hard surfaces thereof and have ample chambers for ingrowth of blood capillaries and bone graft material to expedite bone ingrowth during a post-operative period. The devices do not require anchoring screws or penetration through the hard faces of the vertebrae and can be mounted inside the vertebral disc or along the side of a partially excised disc, or in the disc space of a completely excised disc.

I claim as my invention:

1. A prosthetic device to integrate with and support vertebrae in a vertebral column which comprises a plurality of inert generally oval shaped rings conforming in shape and size with hard end plates of vertebrae on which it is to be seated, each of said rings having ridged top and bottom faces adapted to selectively interdigitate with surfaces of adjacent rings to form a stack and having peaks to bite into the end plates of adjoining vertebrae together with valleys between the peaks to receive bone ingrowth from the vertebrae for fusing the vertebrae together through the rings.

2. The device of claim **1**, wherein the peaks have side walls diverging at an angle of not substantially less than about 30°.

3. The device of claim **1**, wherein the top and bottom faces of the rings fully mate together when the rings are used in a stack.

4. A prosthetic device for vertebral fusion which comprises a stack of annular rigid inert plugs having interiors and interdigitated ridged faces holding the plugs against displacement in the stack and ridged exposed end faces for bottoming on adjoining vertebrae, and a connecting bar extending through the stack holding the plugs in aligned position in the stack.

5. The prosthetic device of claim **4**, wherein each of the plugs have diametrically opposed internal upstanding grooves receiving the connecting bar.

6. The prosthetic device of claim **4**, wherein the plugs have an internal connecting bar divides the interiors of the annular plugs into side by side compartments.

7. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone ingrowth, said plug selected from the group consisting of oval and hemi-oval rings, and said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space.

8. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone ingrowth; said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space, and said height of the annular plug being sufficient to stretch a annulus fibrosis tissue of a disc connecting the adjoining vertebrae to maintain a desired disc height and provide snug gripping of the plug with the and faces of the adjoining vertebrae.

9. The surgical prosthetic device of claim **8** wherein the top and bottom faces of the plug have diverging equally sloping side walls converging to sharp peaks ,and relatively wide valleys between the peaks and said side walls adapted to nest together to hold adjacent plugs in alignment.

10. A surgical prosthetic device adapted for fusing together adjoining vertebrae in a vertebral column which comprises a rigid inert annular plug having an interior and sized and shaped to fit opposed end faces of vertebrae in a vertebral column and having top and bottom faces with peaks adapted to bite into the end faces of the adjoining vertebrae and valleys between the peaks to receive bone growth, said plug having a height effective to provide a strut between the vertebrae maintaining a desired disc space, and said plug having a bar intersecting the interior of the plug.

11. The surgical prosthetic device of claim **10** having diametrically opposed upstanding internal grooves adapted to receive said bar.

12. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, said aperture and slot in the plug adapted to be packed with bone graft material, and said plug being composed of a radiolucent plastics material.

13. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot in each end wall therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, and said aperture and slot in the plug adapted to be packed with bone graft material.

14. A prosthetic device seating on hard end plates of vertebrae in a vertebral column while preserving healthy disc tissue between the vertebrae which comprises a rigid inert annular plug generally conforming in shape and size with opposing hard end plates of vertebrae on which it is to be seated, said plug having peripheral side and end walls, top and bottom faces, a central aperture therethrough between the faces, and a peripheral slot therein, said end faces having raised ridges with side walls converging to peaks and valleys between the side walls, said peaks adapted to be bottomed on and bite into the hard end plate faces of vertebrae, tool mounting means in a peripheral wall of the plug, said aperture and slot in the plug adapted to be packed with bone graft material and said plug having an anterior portion higher than the posterior portion to provide a wedging effect when inserted into position between the hard end plate faces of the vertebrae.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,192,327
DATED : March 9, 1993
INVENTOR(S) : John W. Brantigan

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Column 8:
Claim 8, line 11 "a annulus" should read --annulus--.

line 14, "and faces" should read --end faces--.

Signed and Sealed this

Thirtieth Day of August, 1994

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT
I

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketoneetherketoneketone (PEKEKK), Carbon Fiber Filled	Overview - Polycarbonate, Carbon Fiber Reinforced
Physical				
1	Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	--
Mechanical				
5	Hardness, Rockwell R	--	--	118 - 120
6	Tensile Strength, Ultimate (MPa)	218	183 - 269	83 - 200

7	Tensile Strength, Yield (MPa)	--	--	110
8	Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	Modulus of Elasticity (GPa)	--	12.4 - 26.2	4.8 - 24.1
10	Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	Compressive Yield Strength (MPa)	--	--	114 - 152
13	Izod Impact, Notched (J/cm)	--	1 - 1.1	0.48 - 1.87
14	Izod Impact, Notched (ISO) (kJ/m²)	9	--	--
15	Izod Impact, Unnotched (J/cm)	--	8 - 9.1	2.94 - 9.5
16	Izod Impact, Unnotched (ISO) (kJ/m²)	43.2	--	--
17	K (wear) Factor	--	5000	--
Electrical				
18	Electrical Resistivity (ohm-cm)	5500	100000	5 - 1e+010
19	Surface Resistance (ohm)	--	--	5 - 1e+010
Thermal				
20	CTE, linear 20°C (µm/m-°C)	--	--	13 - 31
21	Thermal Conductivity (W/m-K)	--	--	0.55 - 0.72
22	Maximum Service Temperature, Air (°C)	--	--	100 - 149
23	Deflection Temperature at 0.46 MPa (66 psi) (°C)	--	--	141 - 151
24	Deflection Temperature at 1.8 MPa (264 psi) (°C)	--	271 - 354	100 - 149

25	Glass Temperature (°C)	--	--	150
26	Flammability, UL94	--	V-0	HB - V-0
Processing				
27	Processing Temperature (°C)	--	--	300 - 318
28	Mold Temperature (°C)	--	--	85 - 121
29	Drying Temperature (°C)	--	--	120
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